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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,975	02/13/2002	Anilhai S. Patel	1746	6901
26356	7590	06/28/2004		EXAMINER
ALCON RESEARCH, LTD. R&D COUNSEL, Q-148 6201 SOUTH FREEWAY FORT WORTH, TX 76134-2099			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No.	Applicant(s)	
	10/074,975	PATEL, ANILBHAI S.	
	Examiner	Art Unit	
	Patricia M Bianco	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 February 2002.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-24 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 13 February 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/02/06/02/09/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the port on the tubing (as claimed in lines 3-4 of claim 1) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

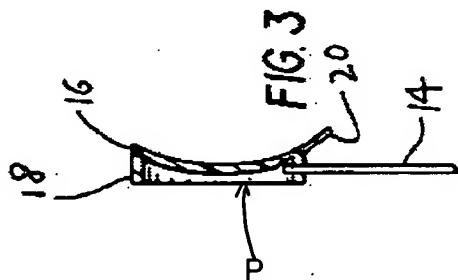
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 5, 12, 15 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Krupin (5,454,796). Krupin discloses an implant 10 for treating glaucoma comprising a body 12 defining a bottom (16), walls (18) integral with the bottom and defining an interior portion (P), and a tube (14) attached thereto.



Krupin further teaches that the implant device is made of a soft surgical grade polymeric resin material, such as polypropylene or silicone.

Claims 1-3, 5, 13 & 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Ethier et al. (6,544,208 B2). Ethier discloses a shunt (10) having a housing (18) with side walls (12), a bottom plate (14), defining a hollow interior and a tube (16) attached to the housing. The implant is made of a flexible plastic or rubber material, such as polymethyl methacrylate, or Silastic® (a silicone like material) or any other bioinert material suitable for placement in the eye.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-12 & 14-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krupin ('796). Krupin discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the material of the implant comprises any of the following: polycarbonate, a soft acrylic, stainless steel, titanium, a hydrogel, polyurethane, polyamide, and a coating. Since Krupin teaches that the implant may be made of a soft surgical grade polymeric resin material, at the time of the invention, it would have been obvious to one having ordinary skill in the art at the time

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the invention was made to make the implant of any of the polymeric resins polycarbonate, a soft acrylic, stainless steel, titanium, a hydrogel, polyurethane, polyamide, and a coating, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 5, 9, 10, 15, 19 & 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krupin ('796) in view of Nigam (6,007,510). Krupin discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the material of the implant comprises a hydrogel or polyurethane. Nigam discloses an implantable fluid shunting device wherein the components may be made of polyurethane, hydrogel, silicones and many other materials that are biocompatible. Since Krupin teaches that the implant may be made of a soft surgical grade polymeric resin material, at the time of the invention, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of a hydrogel or polyurethane as taught by Nigam, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 4-12 & 14-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ethier et al. ('208). Ethier et al. discloses the invention substantially as claimed,

see rejection *supra*, however, fails to disclose specifically that the material of the implant comprises any of the following: polycarbonate, a soft acrylic, stainless steel, titanium, a hydrogel, polyurethane, polyamide, and a coating. Since Ethier et al. teaches that the implant may be made of any bioinert materials, at the time of the invention, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of any of the bioinert materials polycarbonate, a soft acrylic, stainless steel, titanium, a hydrogel, polyurethane, polyamide, and a coating, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 5, 9, 10, 15, 19 & 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ethier et al. ('208) in view of Nigam (6,007,510). Ethier et al. discloses the invention substantially as claimed, see rejection *supra*, however, fails to disclose specifically that the material of the implant comprises a hydrogel or polyurethane. Nigam discloses an implantable fluid shunting device wherein the components may be made of polyurethane, hydrogel, silicones and many other materials that are biocompatible. Since Ethier et al. teaches that the implant may be made of any bioinert materials, at the time of the invention, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of a hydrogel or polyurethane as taught by Nigam, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of

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its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

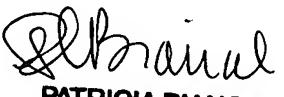
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 22nd, 2004



PATRICIA BIANCO
PRIMARY EXAMINER

Patricia M Bianco
Primary Examiner
Art Unit 3762